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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,175	02/16/2006	Frederic Henot	37998-237505	1959
26694 7590 12/18/2009 VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998				
EXAMINER				
WEN, SHARON X				
ART UNIT		PAPER NUMBER		
1644				
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12/18/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/561,175

Applicant(s)

HENOT ET AL.

Examiner

SHARON WEN

Art Unit

1644

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17, 22, 23 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-17, 22-23 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ ~~Notes of Informal Patent Application~~
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment, filed 09/02/2009, has been entered.
Claims 1-14, 18-21 and 24-26 have been canceled.
Claims 15-17, 22-23 and 27-30 are pending and currently under examination as they read a pharmaceutical composition comprising grass allergen and tree allergen.
2. This Action will be in response to Applicant's Arguments/Remarks, filed 09/02/2009.
The rejections of record can be found in the previous Office Action.
3. The previous rejection under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment, filed 09/02/2009

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 15-17, 23, 27-30 stand rejected under 35 U.S.C. 102(e) as being anticipated by Focke et al. (U.S. Patent 7,244,431 B2, see entire document).

Applicant's argument has been carefully considered but has not been found convincing for reasons of record and reiterated herein for Applicant's convenience.

It is noted that Applicant elected grass allergen as the specific antigen in the claimed pharmaceutical composition. However, given the applicability of the prior art under 103(a) and the broadest reasonable interpretation of the claims, the following grounds of rejection are set forth.

Focke et al. taught a pharmaceutical composition comprising a peptide (i.e., a birch tree allergen) having a molecular weight (MW) of less than 10 KDa

wherein the peptide is a fragment of a protein (see, e.g., claim 1 and column 2, lines 62-67). It is noted the prior art peptide recited in claim 1 would have a MW of less than 10 kDa, given that it is 8 to 50 amino acids in length and that an amino acid has the average MW of 135 dalton. Therefore the peptide taught by the prior art inherently weighs less than 10 kDa. Furthermore, the prior art taught the amount of the peptide in the pharmaceutical composition to be in the range of 0.001-1000 ug and 1-100 ug (see, e.g., column 3, lines 44-47). Lastly, the prior art taught the pharmaceutical composition to be formulated for sublingual, oral or nasal administration which reads on buccal and enteric administration as recited in the present claims, under the broadest reasonable interpretation (see paragraph bridging columns 3-4).

In response to Applicant's argument that the present claims require hydrolysed fragments of allergens, it is noted that such limitation is a product-by-process limitation wherein the allergen is obtainable by hydrolysis with chymotrypsin or any other protease". Since the reference taught a pharmaceutical composition comprising the one or more substances, i.e. birch tree allergens, the same substances obtainable by hydrolysis with chymotrypsin or any other protease would also be anticipated by the reference. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Furthermore, Applicant argues that the prior art did not teach the pharmaceutical composition in a buccal or enteric formulations. In response, it is noted that the sublingual, oral and nasal administration reads on buccal or enteric formulation under the broadest reasonable interpretation. Particularly, one of ordinary skill in the art would have recognized that a composition formulated for sublingual administration would also have been formulated for buccal administration. Moreover, the fact that some cases of enteric administration as Applicant asserted, is performed using a suppository formulation, does not exclude oral or sublingual administration because these administration routes would also allow the antigen to reach the intestine.

Applicant's argument has not been found convincing. Therefore the rejection of record is hereby maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15-17, 22, 23 and 27-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Focke et al. (U.S. Patent 7,244,431) and Marx (U.S. Patent 5,898,037, reference of record).

Applicant's argument has been carefully considered but has not been found convincing for reasons of record and reiterated herein for Applicant's convenience.

The teaching of Focke et al. has been discussed supra (see above).

The only differences between Focke et al. and the present claims are 1) Focke did not explicitly teach grass allergen as the specific antigen in the claimed pharmaceutical composition and 2) Focke et al. did not teach adding nucleoside triphosphates in the pharmaceutical composition.

Regarding grass allergen, the following is noted:

Even though Focke did not explicitly teach grass allergen, Focke stated that "allergenic proteins that can be envisaged are e.g. the major grass pollen..." (see column 2, lines 31-32). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention was made, upon reading Focke et al., to substitute grass allergen for birch allergen (a tree allergen) in an allergy vaccine preparation for the same purpose of treating allergic disorders.

Furthermore, it would be obvious to pick from a finite number of identified allergens to try as taught by Focke et al. because, with a reasonable expectation of success, a person of ordinary skill has good reason to pursue the known options (e.g. preparing a pharmaceutical composition comprising a peptide/allergen that is less than 10 KDa and known allergens such as grass allergen, tree allergen, etc.) within his or her technical grasp. This leads to the anticipated success of making a pharmaceutical composition comprising a grass allergen that is less than 10 KDa. It is likely the product not of innovation but of ordinary skill and common sense.

Regarding nucleoside triphosphates, the following is noted:

Nucleoside triphosphates, such as ATP, were well-known adjuvants in a pharmaceutical composition formulated for treating allergic disorders as evidenced by Marx (see entire document, in particular, Detailed Description of Preferred Embodiments). Specifically, Marx teaches that ATP, a nucleoside triphosphate, is a preferred adjuvant in a composition suitable for treating allergic skin condition which reads on allergic reaction as a *species reads on a genus* (see column 5, lines 4-10 and lines 52-55).

Given the teaching by Focke on the pharmaceutical composition comprising tree or grass allergens for treating allergic reaction and the teaching by Marx on using ATP as an adjuvant for immunotherapy associated with allergic reaction, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to make a pharmaceutical composition comprising tree or grass allergens and nucleoside triphosphates such as ATP for immunotherapy associated with allergic reaction.

Furthermore, given the teaching by Focke et al. that the aim of the sublingual immunotherapy with grass allergens is to elicit protective antibody production (see column 1, lines 35-37), and that the teaching by Marx that ATP is a preferred adjuvant for treating allergic conditions (see column 5, lines 4-10 and lines 52-55), one of ordinary skill would have been motivated to add nucleoside triphosphates such as ATP in a pharmaceutical composition comprising grass allergen for sublingual immunotherapy.

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's argument and Examiner's rebuttal are essentially the same as above.

In response to Applicant's argument that the present claims require hydrolysed fragments of allergens, it is noted that such limitation is a product-by-process limitation wherein the allergen is obtainable by hydrolysis with chymotrypsin or any other protease". Since the reference taught a pharmaceutical composition comprising the one or more substances, i.e. birch tree allergens, the same substances obtainable by hydrolysis with chymotrypsin or any other protease would also be anticipated by the reference. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Furthermore, Applicant argues that the prior art did not teach the pharmaceutical composition in a buccal or enteric formulations. In response, it is noted that the sublingual, oral and nasal administration reads on buccal or enteric formulation under the broadest reasonable interpretation. Particularly, one of ordinary skill in the art would have recognized that a composition formulated for sublingual administration would also have been formulated for buccal administration. Moreover, the fact that some cases of enteric administration as Applicant asserted, is performed using a suppository formulation, does not exclude oral or sublingual administration because these administration routes would also allow the antigen to reach the intestine.

Applicant's argument has not been found convincing. Therefore the rejection of record is hereby maintained.

Conclusion

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

/Sharon Wen/

Examiner

Art Unit 1644

December 15, 2009

/Phillip Gambel/

Primary Examiner

Technology Center 1600 / Art Unit 1644

December 16, 2009